

### **REMARKS**

Applicant respectfully requests reconsideration. Claims 1, 6, 11, 16, 21, 52, 55, 57, 62-68 and 71-75 were previously pending in this application. Claim 11 has been amended to indent the “comparing” step. No claims have been cancelled or added. As a result, claims 1, 6, 11, 16, 21, 52, 55, 57, 62-68 and 71-75 are pending for examination with claims 1, 11, 21, and 68 being independent claims. No new matter has been added.

#### **Rejections under 35 U.S.C. §112**

Claim 11 is rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, the Examiner alleges that it is unclear whether or not the “comparing” of the claim is actually a step or not as it is not indented.

Without conceding the correctness of the rejection, and solely to expedite prosecution, Applicant has amended claim 11 to indent the “comparing” step. Accordingly, withdrawal of the rejection of claim 11 under 35 U.S.C. §112 is respectfully requested.

#### **Rejections Under 35 U.S.C. §102**

Claims 1, 6, 16, 21, 52, 55, 57, 62-68, and 71-75 are rejected under 35 U.S.C. §102 as being anticipated by Ford (1999). The Examiner alleges that “the new ‘predicting’ limitation of the claims is clearly a mental step that does not separate the claimed method from the method of the prior art” (page 2 of the Office Action).

Applicant respectfully disagrees. MPEP § 2131 states that “‘A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.’ Verdegaal Bros. v. Union Oil Co. of California, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987)” (emphasis added). For anticipation of a claim, each and every element of the claim must be found in the cited art. “‘All words in a claim must be considered in judging the patentability of that claim against the prior art.’ In re Wilson, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970).” “The presence of a mental step does not detract from patentability”. Prometheus Labs. v. Mayo Collaborative Servs., 581 F.3d 1336, 1348 (Fed.

Cir. 2009). Applicant respectfully submits that the Examiner has not provided any basis for disregarding the “predicting” limitation of the claims in judging the novelty of the claims.

The instant claims are directed to methods for predicting an individual’s risk profile of developing future diabetes or a diabetic complication comprising obtaining a level of CRP in a blood sample from an individual and predicting whether the individual has an increased risk of developing future diabetes or a diabetic complication if the level of CRP is about 0.30 mg/dl or higher, wherein the individual is free of diabetes.

Ford did not address the possibility of using CRP levels to predict the risk of developing future diabetes in individuals who do not have the disease. Ford does not teach that a specific CRP serum concentration (about 0.30 mg/dl) can be used as a significant predictor of future diabetes in individuals who are free of diabetes. Thus, Ford does not anticipate the instant claims because the reference does not teach each and every element of the instant claims.

Accordingly, withdrawal of this rejection is respectfully requested.

Claims 21, 55, 62, 68, and 71-75 are rejected under 35 U.S.C. §102(b) as being anticipated by Connolly et al. (1988). The Examiner alleges that Connolly et al. teaches obtaining levels of C-reactive protein in a blood sample and predicting that the patient would benefit from the administration of the anti-inflammatory auranofin.

Applicant respectfully disagrees. Contrary to the Examiner’s assertion, Connolly et al. do not address the possibility of using CRP levels to predict whether the patient would benefit from the administration of an anti-inflammatory agent. Connolly et al. does not teach that a specific CRP serum concentration (about 0.30 mg/dl) can be used as a significant predictor of whether a patient would benefit from the administration of an anti-inflammatory. The studies of Connolly et al. are limited to the finding that adjuvant induced arthritic rats had abnormally high plasma concentrations of CRP and treatment with auranofin reduced the level of CRP. Connolly et al. do not teach the use of CRP levels to predict whether the patient would benefit from the administration of the anti-inflammatory auranofin. Connolly et al. does not disclose that a specific CRP serum concentration (about 0.30 mg/dl) can be used to assess whether patients would benefit from the administration of

an anti-inflammatory agent. Thus, Connolly et al. does not anticipate the instant claims because the reference does not teach each and every element of the instant claims.

Accordingly, withdrawal of this rejection is respectfully requested.

**CONCLUSION**

A Notice of Allowance is respectfully requested. The Examiner is requested to call the undersigned at the telephone number listed below if this communication does not place the case in condition for allowance.

If this response is not considered timely filed and if a request for an extension of time is otherwise absent, Applicant hereby requests any necessary extension of time. If there is a fee occasioned by this response, including an extension fee, the Director is hereby authorized to charge any deficiency or credit any overpayment in the fees filed, asserted to be filed or which should have been filed herewith to our Deposit Account No. 23/2825, under Docket No. B0801.70238US00.

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Respectfully submitted,

By



Roque El-Hayek

Registration No.: 55,151

WOLF, GREENFIELD & SACKS, P.C.

600 Atlantic Avenue

Boston, Massachusetts 02210-2206

617.646.8000